MEMORANDUM

To: Members, Subcommittee on Criminal Justice, Drug Policy and Human Resources
From: Mark E. Souder, Chairman
Date: May 17, 2006
Re: Hearing entitled "RU-486 - Demonstrating a Low Standard for Women's Health?"

On Wednesday, May 17, 2006 at 2:00pm in Room 2203 of the Rayburn House Office Building, the Subcommittee on Criminal Justice, Drug Policy and Human Resources will hold a hearing entitled "RU-486 - Demonstrating a Low Standard for Women's Health?" The hearing will discuss the deaths and adverse events associated with RU-486, and the relevant FDA actions regarding the drug. A representative from the FDA Center for Drug Evaluation and Research will testify. Also testifying are physicians, the father of a deceased victim, a legal scholar, and a representative from Danco, the manufacturer of RU-486.

BACKGROUND

I. INTRODUCTION

On December 21, 2005, Congressman Mark Souder, Chairman of the Subcommittee on Criminal Justice, Drug Policy and Human Resources, sent a letter[1] of inquiry to Mr. Andrew von Eschenbach, M.D., the acting Commissioner of the U.S. Food and Drug Administration in response to reports of the deaths of four American women after taking RU-486 to chemically induce an abortion. The letter asked for more detailed information relating to the deaths, the reported deaths of women in Canada and Britain, and other reported adverse events associated with the use of RU-486.

In response to this and subsequent requests for information, the FDA has acknowledged the deaths of eight women associated with the drug, nine life-threatening incidents, 232 hospitalizations, 116 blood transfusions, and 88 cases of infection.[2] These and other cases have added up to a total of 950 adverse event reports (AERs) as of March 31, 2006. These reports are based on the FDA's Adverse Event Reporting System, a voluntary system, with inherent underreporting.

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[1] Letter from Congressman Mark Souder, Chairman of the Subcommittee on Criminal Justice, Drug Policy and Human Resources, to Andrew von Eschenbach, M.D., (Dec. 21, 2005), at http://reform.house.gov/CJDPHR/News/DocumentSingle.aspx?DocumentID=38547.

[2] Letter from David W. Boyer, Assistant Commissioner for Legislation, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, (May 2, 2006) (on file with Subcommittee).

At least five of the deaths following the use of RU-486 have been the result of a toxic shock-like syndrome initiated by the bacteria *Clostridium Sordellii.* This bacteria is thought to exist in low numbers in the reproductive tracts of many women, and is normally combated by the immune system.[3] Experts in immunology,[4] pharmacology,[5] and maternal-fetal medicine[6] have suggested that because RU-486 interferes with the immune response, the bacteria, if present, is allowed to flourish, causing a widespread, multi-organ infection in the woman.

100% fatality rate: The infections are not accompanied by a fever, and symptoms match those that are expected after taking the RU-486 regimen (cramping, pain, bleeding, nausea, vomiting). Each of the women infected with C. Sordellii after RU-486 were dead within 5-7 days. To investigate the nature of this bacteria, the CDC held the "Emerging Clostridial Disease" workshop on May 11, 2006.[7] Workshop presenters noted that the rapid growth of the C. Sordellii bacteria likely forecloses effective treatment; that there is no currently identifiable "window of opportunity" for treatment once a woman is infected, even with major interventions such as hysterectomy. The fatality rate has been 100% for the women who contracted C. Sordellii infection after RU-486. The presenters at the CDC's scientific workshop also noted that antibiotic prophylaxis was unlikely to provide any protection in the RU-486/C. Sordellii context.

II. WHAT IS RU-486?

RU- 486 is the trade name for mifepristone, which in the United States is marketed as Mifeprex. It is produced by Danco Laboratories, which is a corporate entity located in

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[3] Letter to the Editor, James A. McGregor and Ozlem Equiles, *Risks of Mifepristone Abortion in Context*, Contraception 2005, 71: 161.

[4] *See,* Jeanette I. Webster and Esther M. Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, Journal of Endocrinology 2004, 181:207-221 ("Natural and synthetic glucocorticoids protect against the lethal effects of many bacterial and viral components...agents that block the hypothalamic-pituitary-adrenal axis, as in…mifepristone…enhance lipopolysaccharide (LPS) and endotoxin lethality and LPS-induced fever. Even the normally endotoxin-nonresponsive C3H/HeJ mice could be made endotoxin sensitive by RU-486.")

[5] *See,* Ralph P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, The Annals of Pharmacotherapy, September 2005, 39:

> "Mifepristone is a potent progesterone antagonist that, in addition to its ability to block glucocorticoid receptors, blocks progesterone receptors...Blockade of progesterone receptors…results in rejection of the developing placenta and death of the embryo. Prolonged ischemia of the decidua and the embryonic placenta causes necrosis [death] of these tissues. Mifepristone also [causes] cervical dilation and liquefaction of the cervical mucus plug. The combined loss of a closed cervix and the protective cervical mucus plug permits contamination of the decidua and the intrauterine necrotic cells with aerobic and anaerobic bacteria from the normal vaginal flora."

[6] *See,* Sharon Worchester, *Mifepristone Deaths Raise Unanswered Questions*, Ob. Gyn. News, (October 1, 2005) at 13. (Quoting Dr. James A. McGregor)("Mifepristone has multiple pharmacologic properties that may interfere with innate immune responses to infection, toxin exposures, and inflammatory stimuli.")

[7] An agenda for the meeting is available at http://www.fda.gov/cder/meeting/clostridial_disease_Agenda_final.pdf.

the Cayman Islands and which produces only Mifeprex.[8] Not to be confused with Plan B emergency contraception,[9] which is intended to prevent the fertilization of an egg or the implantation of a fertilized egg, Mifeprex is approved for the termination of pregnancy through 49 days development. Termination occurs by blocking progesterone absorption, thus blocking nutrition the prenate, killing it. Mifeprex is used in combination with a prostaglandin called misoprostol, which causes contractions that expel the contents of the uterus.[10] This is an off-label use for misoprostol, which contains a black-box warning against using the drug during pregnancy.

Because chemical abortions will fail 3-7.9% of the time, it is implicit that women who take Mifeprex must be eligible for a surgical abortion as well, to complete the abortion procedure in the case of failure.[11]

According to Dr. Tom Tvedten, an abortion provider in Little Rock, Arkansas, "With medical termination, the discomfort is significant because they have to go through mini-labor…There's a lot of hard cramps and usually significant bleeding. It's cheaper, safer and less painful to have a surgical termination."[12] The Mifeprex product information explains,[13] "nearly all of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction," including: abdominal pain; uterine cramping; nausea; headache; vomiting; diarrhea; dizziness; fatigue; back pain; uterine hemorrhage; fever; viral infections; vaginitis; rigors (chills/shaking); dyspepsia; insomnia; asthenia; leg pain; anxiety; anemia; leucorrhea; sinusitis; syncope; endrometritis / salpingitis / pelvic inflammatory disease; decrease in hemoglobin greater than 2 g/dL; pelvic pain; and fainting.[14]

The eight reported deaths in the United States following the use of RU-486 suggests that RU-486 may be almost 14 times more dangerous as surgical abortion for the time period during which it is administered.[15] Despite its side effects and risks and of death, the

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[8] *See, Foes criticize Chinese manufacture of abortion pill for U.S.*, CNN.com, (Oct. 13, 2000) at http://archives.cnn.com/2000/HEALTH/women/10/13/abortionpill.plant.ap/index.html.

[9] For more information, see http://www.go2planb.com/ForConsumers/Index.aspx.

[10] Pfizer (along with their generic subsidiary) and Teva Pharmaceuticals, the makers of misoprostol, have never filed a New Drug Application to seek approval from the FDA for its use in abortion. It was approved for use with ulcers, and is contraindicated for pregnancy. Pfizer's German affiliate recently pulled the drug from the market.

[11] See Planned Parenthood's website, which states that a woman should not have a chemical abortion if she is "unwilling or unable to have a vacuum aspiration abortion if the medication abortion is incomplete," at http://www.plannedparenthood.com/pp2/portal/files/portal/medicalinfo/abortion/pub-medical-abortion.xml.

[12] John Leland, *Under Din of Abortion Debate, an Experience Shared Quietly*, N.Y. TIMES, Sept. 18, 2005, *at* http://www.nytimes.com/glogin?URI=http://www.nytimes.com/2005/09/18/national/18abortion.html&OQ=_rQ3D1&OP=41647c1fQ2FQ2AQ7EklQ2AbBG)ABB7FQ2AFqqjQ2AqQ2FQ2A42Q2A-_7VB-_YQ2A42_lBA7VB-vC7KY. (Quoting Dr. Tom Tvedten of Little Rock, Arkansas).

[13] DANCO LABORATORIES, MIFEPREX PRESCRIBING INFORMATION (2005) (available at http://www.earlyoptionpill.com/pdfs/prescribing071905.pdf.)

[14] *Id.*

[15] The mortality rate for women who procure a surgical abortion is 0.1 in 100,000 during the first eight weeks of pregnancy, the period for which RU-486 is available for women. Dr. Michael Green, based on usage rates of 460,000 and 4 deaths, suggested that the risk of death from chemical abortion is ten times

primary justifications which the abortion industry offers for the use of RU-486 are convenience and increased market access.[16]

III. THE PROCESS BY WHICH RU-486 WAS APPROVED

a. The U.S. Approval Process was Initiated by the Clinton Administration, not the Pharmaceutical Industry

French pharmaceutical maker Roussel Uclaf developed Mifepristone in the 1980s. In 1988, the drug became available to the French market only with reservations on the part of the company's president, and only within the context of "exceedingly tight controls" on the distribution and use of the product.[17] These controls had the specific goal of limiting the widespread use of the drug.[18] In 1989, Roussel directors voted to remove the drug from the market, but after a petition from attendees of a conference on chemical abortion, French Health Minister Claude Evin forced Roussel to retract its withdrawal decision.[19]

In the early 1990s, the chairman of Hoechst Roussel, Roussel Uclaf's German affiliate, officially declared the production of Mifepristone to be incompatible with the ethics of the company.[20] In spite of this, President Bill Clinton, as one of his first official acts as president, directed the Department of Health and Human Services to investigate efforts promoting the testing and licensing of mifepristone or other antiprogestins in the United States.[21] Later, President Clinton, in an unprecedented move, personally appealed to the European makers of RU-486 to market the drug in the United States.[22] Although Hoechst initially refused, they later gave in to pressure[23] from the FDA and Population Council

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greater. *See,* Michael F. Green, M.D., *Fatal Infections Associated with Mifepristone-Induced Abortion*, Dec. 1, 2005, N. ENGL. J. MED 353;22 *at* 2318. Current numbers suggest, however, eight deaths in the United States, while, according to the manufacturer, 575,000 women have used the drug. This works out to 1 in about 71,875, or 1.39 for every 100,000.

[16] *See, e.g.,* PLANNED PARENTHOOD / CAPS MEDICAL ABORTION TRAINING PROGRAM, ISSUE NO. 12, MIFEMATTERS (2005).

[17] André Ulmann, M.D., Ph.D., *The Development of Mifepristone: A Pharmaceutical Drama in Three Acts,* JAMWA 2000; 55:117-120.

[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] *See*, Memorandum for the Secretary of Health and Human Services, "Importation of RU-486," *Public Papers of the Presidents: Administration of William J. Clinton, 1993* (Jan. 22, 1993) at 11.

[22] Letter from President Bill Clinton to Dr. Edouard Sakiz, Chairman, Supervisory Board, Roussel Uclaf, (May 16, 1994) (available at http://reform.house.gov/UploadedFiles/Memo%20from%20Donna%20Shalala,%20HHS%20Secretary%20-%20WEBSITE.pdf). *See also,* André Ulmann, M.D., Ph.D., *The Development of Mifepristone: A Pharmaceutical Drama in Three Acts,* JAMWA 2000; 55:117-120.

[23] *See, e.g.* Memorandum from Donna Shalala, Secretary of Health and Human Services to Carol Rasco, Director of Domestic Policy 5 (Nov. 15, 1993) (available at http://reform.house.gov/UploadedFiles/RU-486%20Memo%20for%20the%20Secretary%20of%20Health%20and%20Human%20Services%20-%20FOR%20WEBSITE.pdf).

> "Unless you object, the Department plans to engage the services of Felix Rohatyn or someone comparable as a negotiator. This negotiator would require the State

(an international reproductive technologies research and advocacy organization) and licensed the RU-486 patent, at no cost (in order to protect itself from liability), to the Population Council to allow them to market the drug in the United States.[24]

b. Approval of RU-486 Under Subpart H, a Process Reserved Explicitly for the Approval of Drugs Intended to Treat Life-Threatening Illnesses

In 1996, the Population Council filed a New Drug Application (NDA) for mifepristone tablets, which the FDA initially accorded standard review. The 2000 mifepristone approvable letter, however, indicated that the FDA had "considered this application under the restricted distribution regulations contained in 21 CFR 314.500 (Subpart H) and [had] concluded that restrictions as per [21] CFR 314.520 on the distribution and use of mifepristone are needed to assure safe use of this product."[25] Approval of Mifeprex was on September 28, 2000, using the accelerated process outlined in Subpart H.

i. Subpart H

In 1992 the FDA issued final regulations under which the agency would accelerate the approval of certain drugs for the treatment of "serious or life-threatening illnesses."

According to the language of Subpart H,

> "This subpart applies to certain new drug products that have been studied for their safety and effectiveness in **treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments** (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy)." 21 CFR 314.500 (1999) (emphasis added).

Department's support in making appropriate diplomatic contacts, both with the United States Ambassadors to France and Germany, the French and German Ambassadors to this country, and other high-level officials in France and Germany, such as the respective Health Ministers. The purpose of such contacts would be to…determine what measures the United States could take to persuade Roussel Uclaf and Hoechst to make RU-486 available in the United States. The French and German governments might be displeased to learn that their companies are not accommodating a request made by the United States Government."

[24] Letter from E.G. Afting, President and CEO, Roussel Uclaf, to President Bill Clinton, (May 9, 1994) (available at http://reform.house.gov/UploadedFiles/Letter%20from%20E.G.%20Afting%20to%20Pres.%20Clinton%20-%20WEBSITE.pdf).

[25] Letter from the Food and Drug Administration, Center for Drug Evaluation and Research, to the Population Council, Attn: Sandra P. Arnold, (Sept. 28, 2000) (available at http://www.fda.gov/cder/foi/appletter/2000/20687appltr.htm).

This regulation became known as Subpart H.[26] The FDA has so far approved 38 New Drug Applications under subpart H. Of these approvals, 20 were for the treatment of HIV and HIV- related diseases, nine were for the treatment of various cancers and their symptoms, four were for severe bacterial infections, one was for erythema nodosum leprosum (leprosy), one was for hypotension, and one (Mifeprex) was for the termination of pregnancy.

The FDA imposed the Subpart H approval process on the RU-486 drug regimen. When made aware of this, the Population Council argued that its application for mifepristone did not fall within the scope of Subpart H, insisting that "…it is clear that the imposition of Subpart H is unlawful, unnecessary, and undesirable."[27]

This contention is consistent with the fact that 21 CFR 314.500 designates Subpart H as an extraordinary process for the approval of drugs meant to treat "serious or life-threatening illness." The problem with the imposition of Subpart H for an abortion pill is, in the words of the Population Council, "[n]either pregnancy nor unwanted pregnancy is an illness, and Subpart H is therefore inapplicable for that reason alone…Neither is pregnancy nor unwanted pregnancy a 'serious' or 'life-threatening' situation as that term is defined in Subpart H."

The FDA was undeterred by the "life-threatening illness" requirement for applying Subpart H to Mifeprex:

> "This subpart applies to certain new drugs that have been studied for their safety and effectiveness in treating serious or life-threatening illness…FDA has determined that the termination of an unwanted pregnancy is a serious *condition* within the scope of Subpart H."[28]

Furthermore, 21 CFR 314.520 provides for approval of drugs on the basis of restricted use of the drug.[29] The FDA imposed several such restrictions on the distribution of Mifeprex.[30]

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[26] 21 CFR § 314.500.

[27] Letter to FDA/CDER, Office of Drug Evaluation III, Division of Reproductive and Urologic Products, from Sandra Arnold, Vice President, Corporate Affairs of the Population Council, (Sept. 6, 2000) [Cited in Citizen Petition re: Request for Stay and Repeal of the Approval of Mifeprex (mifepristone) for the Medical Termination of Intrauterine Pregnancy through 49 Days' Gestation, (Aug. 21, 2002), on file with the subcommittee].

[28] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000) (available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf) (emphasis added).

[29] (a) If FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to assure safe use of the drug product, such as:
(1) Distribution restricted to certain facilities or physicians with special training or experience; or
(2) Distribution conditioned on the performance of specified medical procedures.
(3) The limitations imposed will be commensurate with the specific safety concerns presented by the drug product.
21 CFR § 314.520.

Mifepristone must be provided by or under the supervision of a physician who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately
- Ability to diagnose ectopic pregnancies
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary
- Has read and understood the prescribing information of Mifeprex
- Must provide each patient with a Medication Guide and must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and Patient Agreement, given her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well
- Must notify the sponsor or its designate in writing as discussed in the Package Insert under the heading DOSEAGE AND ADMINISTRATION in the event of an on-going pregnancy, which is not terminated subsequent to the conclusion of the treatment procedure
- Must report any hospitalization, transfusion or other serious events to the sponsor or its designate
- Must record the Mifeprex package serial number in each patient's record

With respect to the aspects of distribution other than physician qualifications described above, distribution of Mifeprex will be in accordance with the system described in the Population Council's submission of March 30, 2000, which includes the following:

- Secure manufacturing, receiving, and holding areas for the drug
- Secure shipping procedures, including tamper-proof seals
- Controlled returns procedures
- Tracking system ability to trace individual packages to the patient level, while maintaining patient confidentiality
- Use of authorized distributors and agents with necessary expertise to handle distribution requirements for the drug
- Provision of drug through a direct, confidential physician distribution system that ensures only qualified physicians will receive the drug for patient dispensing

In addition, the Population Council agreed to several post-marketing studies on the effects of RU-486 on women.[31]

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[30] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000) (available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf) (emphasis added).
[31] *Id.*

The high incidence of adverse events has prompted the manufacturer, in cooperation with the FDA, to take several additional steps to alert women and the medical community to the dangers of the drug:[32]

- "Dear Health Care Provider" Letter, April 19, 2002 (warning of danger of ruptured ectopic pregnancies).
- "Dear Emergency Room Director" Letter, November 12, 2004 (warning of infection, heavy bleeding, and ruptured ectopic pregnancy).
- "Dear Health Care Professional" Letter, November 12, 2004 (warning of infection, heavy bleeding, and ruptured ectopic pregnancy).
- Updated label, December 22, 2004 (reflecting danger of infection, heavy bleeding, and ruptured ectopic pregnancy).

IV. THE FDA'S AUTHORITY TO UNILATERALLY WITHDRAW APPROVAL OF A DRUG.

21 CFR 314.530 names several instances in which the FDA has the authority to withdraw approval of a drug, and RU-486 falls into many of these categories:

(a) (1) A postmarketing clinical study fails to verify clinical benefit;

Since its approval, RU-486 has been associated with the deaths of eight known cases of healthy women.[33] Because women who visit the emergency room present with symptoms virtually identical to those associated with miscarriage,[34] deaths within the U.S. following the use of RU-486 may be much higher, but go unreported.

The mortality rate for surgical abortion for the first eight weeks of pregnancy is 0.1 per 100,000.[35] The makers of Mifeprex report that 575,000 women have used Mifeprex (based on units shipped, not units prescribed, and based on the assumption that one, rather than the FDA-approved three, tablets are administered to the patient;[36] the actual number of women who have taken the drug may be much lower). Using the figure of 575,000 women having taken RU-486, this works out to a known death rate of approximately 1.39 per 100,000, nearly *14 times* greater than surgical abortion. As noted above, Subpart H drug approval is conditioned on "meaningful therapeutic benefit." The statistics demonstrate that medical abortion is far more dangerous than the existing treatment, surgical abortion, which is proof of a lack of clinical benefit.

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[32] See Danco's website, http://www.earlyoptionpill.com/.
[33] Letter from David W. Boyer, Assistant Commissioner for Legislation, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, (May 2, 2006) (on file with Subcommittee).
[34] "Dear Emergency Room Director" Letter from Danco Laboratories to emergency room directors, (Nov. 12, 2004), *at* http://www.fda.gov/cder/drug/infopage/mifepristone/DearER.pdf.
[35] Michael F. Green, M.D., *Fatal Infections Associated with Mifepristone-Induced Abortion*, Dec. 1, 2005, N. ENGL. J. MED 353:22 *at* 2318.
[36] *Id.*

(a)(3) Use after marketing demonstrates that postmarketing restrictions are inadequate to assure safe use of the drug product;

Experience shows that postmarketing restrictions on RU-486 are inadequate to assure the safe use of the product, because the medical community has ignored them on a widespread basis. The National Abortion Federation and the World Health Organization have released separate protocols which recommend the use of Mifeprex beyond the time periods approved by the FDA and which recommend administration techniques also dissonant with the FDA's approved use. While off-label use of drugs is common, it runs contrary to the entire purpose of the regulatory regime approved for Mifeprex under Subpart H.

The FDA is aware of the medical community's refusal to heed the regulations it instated on RU-486. In its own words, the FDA "is aware that…some [physicians] may have chosen to use a modified version of the Patient Agreement form. However, these decisions are made by physicians exercising their own judgment about what is best for their patients**.**"[37] This is contrary to the detailed Risk Management Program, explained in the FDA memo detailing the drug's approval, which states: "the signed agreement form will be given to the patient for her reference and another kept in the medical records," and "[the prescribing physician] must provide each patient…with a copy of the Medication Guide and Patient Agreement, given her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well."[38] The FDA determined that these restrictions were critical to the safe use of the drug, and in spite of this, physicians have refused to heed them.

(a)(4) The applicant fails to adhere to the postmarketing restrictions agreed upon;

Although the FDA stipulated that the manufacturer have tracking systems in place that would track the distribution of Mifeprex "to the patient level," and that require physicians to "record the Mifeprex package serial number in each patient's record,"[39] the manufacturer claims not to have records on the actual usage of Mifeprex.[40] This is evidence of one of two things: that the manufacturer is not tracking the distribution of its products as required by the FDA, or that it is misrepresenting the actual usage of its product in its promotional materials.

In addition to the FDA requiring patients to sign a Patient Agreement form, the Population Council agreed, as part of the approval process, to "auditing prescribers to

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[37] Letter from Patrick Ronan, Associate Commissioner for Legislation Department of Health and Human Services FDA to Hon. Mark E. Souder, (March 16, 2006) (on file with Govt. Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resources).
[38] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000) (available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf).
[39] *Id.*
[40] *See,* Michael F. Green, M.D., *Fatal Infections Associated with Mifepristone-Induced Abortion*, Dec. 1, 2005, N. ENGL. J. MED 353;22 *at* 2318.

ascertain whether they have obtained signed copies of the Patient Agreement forms." It is unclear whether the Population Council, Danco, or any other entity associated with the production of RU-486 has adhered to this requirement.

(5) The promotional materials are false or misleading

The FDA conditioned approval of Mifeprex on the tracking of its usage "to the patient level." In spite of this, the manufacturer estimates the usage of its drug for its promotional materials.[41] This affects the perceived safety of the drug, as the manufacturer may be overstating its actual usage in comparison with the adverse events reported.

This hearing will examine the unsafe characteristics of RU-486, the reported maternal deaths and adverse events associated with it, and FDA's actions regarding the RU-486 abortion regimen since its approval, and its authority to restrict or withdraw the drug.

WITNESSES

Janet Woodcock, M.D., Director Deputy Commissioner for Operations, Food and Drug Administration (FDA);

Monty Patterson, father Holly Patterson, who was 18 years old when she died after taking RU-486;

Donna Harrison, M.D., Member, Mifeprex Subcommittee of American Association of Prolife Obstetricians and Gynecologists;

Susan Wood, Former FDA Asst. Commissioner for Women's Health;

Lisa D. Rarick, M.D., RAR Consulting, LLC;

O. Carter Snead, Assoc. Professor of Law, University of Notre Dame; Former General Counsel for the President's Council on Bioethics.

STAFF CONTACT

Questions may be directed to Michelle Gress at (202) 225-2577.

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[41] Letter from David W. Boyer, Assistant Commissioner for Legislation, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, (May 2, 2006) (on file with Subcommittee); *FDA Announces Mifeprex Not Cause of One of Two Recent Abortion-Related Deaths*, KAISER NETWORK DAILY REPORTS, (April 11, 2006) *at* http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=36534. ("We stand behind the safety profile of the drug, which has been used by approximately 575,000 women in this country since FDA approval in 2000," quoting Cynthia Summers, director of marketing and public affairs at Danco Laboratories, originally in Wall Street Journal, April 11, 2006.)